## REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office action dated December 29, 2005 are respectfully requested. Applicant thanks the Examiner for an indication that claims 15-22, 31, and 34-37 are allowable. Applicant petitions the Commissioner for a 1-month extension of time. A separate petition accompanies this amendment.

I. Amendments

Claim 23 is amended to clarify the method steps. Basis for this amendment can be found on page 13, line 24 through page 14, line 8.

No new subject matter is added by way of these amendments.

II. Rejections under 35 U.S.C. §102

Claims 23 and 25-28 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Anaokar *et al.* (US Patent Application No. 2003/0175153).

Claims 23 and 25-28 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Rittersdorf *et al.* (US Patent No. 5,426,030).

Claims 23 and 25-28 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Kozak *et al.* (US Patent No. 5,460,974).

Claims 23 and 25-28 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Thakore *et al.* (US Patent No. 5,135,716).

These rejections are respectfully traversed for the following reasons.

A. The Invention

The present invention, as embodied by claims 23 and 25-28, relate to a method of measuring serum cholesterol associated with HDL in a blood fluid sample.

B. The Cited Art

ANAOKAR ET AL. describe a multilayer test strip and method for determining the concentration of HDL cholesterol in a blood sample. The test strip includes a

disbursement layer, a two-stage blood separation layer, and a reaction layer arranged vertically.

RITTERSDORF ET AL. relate to an apparatus and method for separating non-HDL from biological fluids. The sample is applied to a separating layer for cellular components and flows through a carrier layer which contains a precipitating agent during which the non-HDL lipoproteins are separated, and into a fiber mesh layer. The test reaction is started by pressing a flap with a test layer onto the mesh layer (see Col. 5, lines 7-12).

KOZAK ET AL. describe a device and method for separating the cellular components of a whole blood sample for assaying HDL. The device includes at least a first separation zone (12) for separating cellular components and a second separation zone (14) that separates the LDL and VLDL fractions from the sample. The sample then flows along a capillary (18) to a test area (20) that includes reagents for quantitating HDL in the sample.

THAKORE ET AL. disclose devices and methods for HDL quantification in a blood fluid sample. In these devices, the fluid sample flows continuously, though an unbroken path, from an inlet well to a carrier for HDL quantification.

C. Analysis

Each of the cited Anaokar *et al.*, Rittersdorf *et al.*, Kozak *et al.*, and Thakore *et al.* references fail to show a method as presently claimed. The present claims, as embodied by amended claim 23, require that the reagent effective to selectively bind and remove non-HDLs is provided in a reagent pad which is separated from the sample collection site. Only after the sample has been distributed to the sample collection site is the reagent pad, and binding reagent contained therein, moved into contact with the sample collection site. This sequence of steps and associated structure for its operation are not fairly taught by the cited references.

Anaokar *et al.* teach a vertical multilayer test strip having a disbursement layer (36) for disbursement of the whole blood or plasma, a two-stage layer (38 and 40) for separating the blood cells from the plasma, and a reaction layer (42) containing

reagents for generating a visible color change in the presence of cholesterol. As seen in Figure 1, the sample contacts, in order, an opening (32), a disbursement layer of woven material (36), two blood separation layers (38, 40), and a reaction layer (42). Nowhere does Anaokar *et al.* teach bringing a laminate comprising a reagent pad and an HDL test pad into contact with a sample collection site. Instead, the layers are in direct contact in the device.

Rittersdorf *et al.* teach an apparatus where the sample flows through a separating layer, a carrier layer containing a precipitating agent, and a fiber mesh layer. The test reaction is started by pressing a test layer onto the mesh layer (see Fig. 1). Rittersdorf *et al.* fail to teach bringing a laminate comprising a reagent pad and a HDL test pad into contact with a sample collection site. As seen in Fig. 1, the carrier layer, corresponding to the reagent pad, is not located on the flap with the test layer.

Kozak *et al.* teach a device whereby a sample contacts a first zone comprising a carrier matrix for filtering the cellular components of a whole blood sample and a second zone comprising a carrier matrix incorporating a precipitating reagent to separate the LDL and VLDL fractions from the sample. The first and second zones are in direct contact. The sample then flows to a test area including an indicator reagent for assay of HDL cholesterol. As seen in Fig. 1, a whole blood sample is introduced through a sample port to the first and second separation areas, which are arranged as a laminar array. The sample is then introduced to the test area through a capillary or by direct contact. Nowhere does Kozak *et al.* teach bringing a laminate comprising a reagent pad and an HDL test pad into contact with a sample collection site. Instead, the second separation zone and the test zone are in contact via a capillary (see Fig. 1) or are in direct contact (see Col. 9, lines 51-56).

As seen in Figure 1 of Thakore *et al.*, the sample contacts, in order, an orifice (12), a physical transportation medium (3), a plasma separation membrane (4) containing LDL and VLDL precipitating reagents, a filter membrane (5) to filter LDL and VLDL precipitates, and a plasma collecting test membrane (6) containing the reagents. Thakore *et al.* fail to teach bringing a laminate into contact with a sample collection site.

In view of the above, Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. §102.

III. Obviousness-type Double Patenting Rejections

Claims 1, 4-14, 23-24, 26, 29-30, and 32-33 were rejected under the judicially created doctrine of obviousness-type double patenting as being directed to an invention not patentably distinct from claims 1-6, 8, 10, 13-16, 20-21, 24, and 26-28 of co-owned U.S. Patent No. 6,881,581.

Claims 1 and 4-14, 23-24, 29-30, and 32-33 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being directed to an invention not patentably distinct from the pending claims 1, 3-10, 12-14, 17-21, and 24-25 of co-pending U.S. Application No. 10/410,671.

A Terminal Disclaimer prepared in accordance with 37 C.F.R. §1.321(b) and (c) is enclosed. The signed Terminal Disclaimer obviates this obviousness-type double patenting rejection.

IV. Conclusion

In view of the foregoing, Applicant submits that the claims pending in the application are in condition for allowance. A Notice of Allowance is therefore respectfully requested.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4410.

Respectfully submitted,

Jacqueline F. Mahoney

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Jacqueline F. Mahoney
Registration No. 48,390

**Correspondence Address:**
Customer No. 22918